

Notice of Allowability

Application No.

10/028,224

Examiner

David J. Steadman

Applicant(s)

BENSON ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 12/16/2005.
2. ☒ The allowed claim(s) is/are 108.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of the Application

- [1] Applicant's petition to revive an unintentionally abandoned application, filed on 12/16/2005, is granted as acknowledged in the Office communication mailed on 3/23/2006.
- [2] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- [3] Claim 108 is pending in the application.
- [4] Applicant's amendment to the claims, filed on 12/16/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [5] In view of applicant's amendment to the claims, the rejections set forth in the Office action mailed on 4/19/2005 are withdrawn.

Reasons for Allowance

- [6] The following is an Examiner's statement of reasons for allowance. Claim 108 is drawn to a crystal of SEQ ID NO:1 co-crystallized with the ligand of Figure 1 having trigonal space group symmetry $P3_221$ and the unit cell dimensions of $a=b=112 \text{ \AA} \pm 20 \text{ \AA}$, $c=110 \text{ \AA} \pm 20 \text{ \AA}$, $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$. The claim encompasses a genus of crystals having the vector lengths of a, b, and c as encompassed by the claims. The examiner acknowledges that the claim allows for approximately 35% variation in the lengths of vectors a, b, and c. However, it is noted that the specification discloses that numerous

crystals of SEQ ID NO:1 co-crystallized with the inhibitor of Figure 1 were obtained having vector lengths of a, b, and c over the recited ranges of variation (see specification at p. 45, line 22 to page 47, line 12). Put another way, the variation of vectors a, b, and c in claim 108 is based on the data collected from a plurality of crystals that exhibited vector lengths of a, b, and c as recited in the claim.

Also, it is noted that the specification defines vectors a and b independently throughout the original application. See, e.g., p. 47 of the specification. However, claim 108 interrelates the values of a and b, reciting a as being equal to b. MPEP § 2163 states that “there is no *in haec verba* requirement” for newly added claim limitations, only that “newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure” (MPEP 8th Ed., October 2005 Revision, p. 2100-175). According to the same section of the MPEP, “[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 156364, 19 USPQ2d at 1117.” While the specification fails to provide explicit disclosure for such a limitation, the vector lengths of a and b in a crystal with a trigonal space group symmetry, such as the instantly claimed crystal, are necessarily equal to each other, which was well-known at the time of the invention. See the examiner’s search note filed on 8/5/2003, which shows that the values of a, b, and c in a crystal with a trigonal space group have $a = b \neq c$. Thus, the specification provides implicit or inherent disclosure for this claim limitation.

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The examiner has found no teaching or suggestion in the prior art directed to a crystal of beta-secretase as encompassed by the claim. Therefore, claim 108, directed to a crystal of SEQ ID NO:1 co-crystallized with the ligand of Figure 1 having trigonal space group symmetry $P3_221$ and the unit cell dimensions of $a=b=112 \text{ \AA} \pm 20 \text{ \AA}$, $c=110 \text{ \AA} \pm 20 \text{ \AA}$, $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$ is allowable over the prior art of record.

[7] Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656